DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 2, 2016

Exactech, Incorporated
Mr. Graham Cuthbert
Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

Re: K073688
Trade/Device Name: Equinoxe Reverse Shoulder System Fracture Humeral Adapter Tray and Fracture Humeral Adapter Tray Locking Screw
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT
Dated: January 31, 2008
Received: February 1, 2008

Dear Mr. Cuthbert:

This letter corrects our substantially equivalent letter of February 29, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Summary of Exactech® Equinoxe Reverse Shoulder
Fracture Humeral Adapter Tray and Fracture Humeral Adapter Locking Screw
Special 510(k) - Indications for Use

510(k) Number: K073686

Device Name: Equinoxe Reverse Shoulder System Fracture Humeral Adapter Tray and Fracture Humeral Adapter Tray Locking Screw

INDICATIONS FOR USE:
The Exactech Equinoxe™ Reverse Shoulder System is indicated to relieve pain and restore function in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe™ Reverse Shoulder is also indicated for failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

Prescription Use ___X___ **and/or** **Over-The-Counter Use** ___No___
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucheit for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073686

K073688

Summary of Exactech® Equinoxe Reverse Shoulder Fracture Humeral Adapter Tray and Fracture Humeral Adapter Locking Screw Special 510(k) - 510(k) Summary

Sponsor: Exactech® Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Phone: (352) - 377 - 1140
Fax: (352) - 378 - 2617

FDA Establishment Number 1038671

Contact: Graham Cuthbert
Regulatory Representative

Date: December 17, 2007

Summary of Exactech® Equinoxe Reverse Shoulder Fracture Humeral Adapter Tray and Fracture Humeral Adapter Locking Screw Special 510(k) - 510(k) Summary

Trade or proprietary or model name(s):
Equinoxe Reverse Shoulder Fracture Humeral Adapter Tray and Fracture Humeral Adapter Locking Screw

Common Name
Shoulder Joint Prosthesis

Classification name
Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR 888.3650, Class II, Product Code KWT)
Prosthesis, Shoulder, Semi-constrained, metal/polymer cemented (21 CFR 888.3660, Class II, Product Code KWS)

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K063569	Exactech Equinoxe™ Reverse Shoulder System	Exactech, Inc.

Indications for Use:
The Exactech Equinoxe™ Reverse Shoulder System is indicated to relieve pain and restore function in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe™ Reverse Shoulder System is also indicated for failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

Device Description:
The Equinoxe™ fracture adapter tray connects to the Equinoxe™ fracture humeral stems via a morse taper and a non-breakaway locking screw using a 5/16-18 thread instead of the primary adapter tray connecting to the primary/revision humeral stems via a spherical taper and a breakaway locking screw using a M6 thread

Substantial Equivalency Conclusion:

Engineering evaluations were conducted to verify that the performance of the proposed components would be adequate for anticipated *in vivo* use. Based on successful results discussed in this submission, we conclude that the proposed devices are substantially equivalent to the previously cleared predicates.